Career Opportunity

Phebra develops, manufactures, and supplies high quality and innovative pharmaceuticals to meet the requirements of the hospital specialty pharmaceutical market. At Phebra we create critical medicines which save and improve lives. Working with us, you will have an opportunity to contribute and make a difference!

The following role is currently available. If you feel you meet the below criteria, we welcome applications from those presently employed at Phebra and applicants currently external to the business. Please feel free to share this information with people you know who may be interested in applying for this role.
Please apply by sending your resume and a covering letter to address how you meet the requirements of the role to HR@phebra.com

Role Title	**Regulatory Affairs Associate**		
Department	Regulatory Affairs		
Hiring Manager	Praneel Sharma (Regulatory Affairs Manager)		
Job code	INT40	**Closing Date**	30 May 2025
About the role	The role of **Regulatory Affairs Associate** at Phebra is a permanent full-time (37.5 hrs per week) opportunity working onsite at our head office and manufacturing facility in Lane Cove, Sydney. To be successful within the role we require a proactive and strategic thinker who can contribute to the success of our strategic plan, working co-operatively with the wider team to achieve this. The role is responsible for various regulatory activities including, but not limited to: ▪ Preparation of submissions for, and liaison with, the Australian regulatory authorities. ▪ Involvement in determining strategic elements of submissions, such as timelines, routes of submission etc, ▪ Ensuring continual regulatory compliance, undertaking reviews of existing registration dossiers and preparation of gap analysis and change control assessments for potential product change applications (where relevant) ▪ Generation of variation applications for prescription, OTC and full spectrum of regulatory activities across various therapeutic areas. ▪ Generate, review and maintain Product Information and Consumer Medicines Information documents ▪ Maintain and update regulatory product files within the regulatory storage facility and responsibility for the maintenance of the databases related to regulatory activities.		
About you	Our ideal candidate would be someone who can think outside of the box, be pragmatic and solutions-oriented who is agile and flexible in approach as well as having the following requirements: - Minimum degree qualification in any scientific discipline - 3 + years' experience with Regulatory Affairs roles working within the **prescription pharmaceutical industry in Australia and New Zealand** (consideration also given to applicants who have comparable overseas markets, eg. US, Canada, Switzerland, UK) - Good understanding and knowledge of GMP and Chemistry Manufacturing and Controls (CMC) - Understanding of ICH and local guidelines - Experience working with the TGA and Medsafe - Strong technical/dossier writing and review skills - Experience with eCTD publishing and Regulatory Information Management System (RIMS) - Project management skills preferred but not essential - Full working rights in Australia are essential		

Phebra are an equal opportunities employer, we are committed to diversity and inclusion within the workplace and believe that a diverse team with unique perspectives, ideas and experiences should be valued.